ALABAMA PUBLIC HEALTH

MONOCLONAL ANTIBODY COVID-19 TREATMENT FOR NON-HOSPITALIZED PATIENTS

There are currently three monoclonal antibody products under Emergency Use Authorization (EUA) for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) who have tested positive for COVID-19 and who are at high risk for progression to severe COVID-19, including hospitalization or death. The definition of high risk may vary slightly with each product and EUA. Examples include:

- Have a body mass index (BMI) > 35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are >65 years of age
- Are >55 years of age AND have
  - Cardiovascular disease, OR
  - Hypertension, OR
  - Chronic obstructive pulmonary disease/other respiratory disease.
- Are 12 – 17 years of age AND have
  - BME>85 percentile for their age and gender based on CDC growth charts, OR
  - Sickle cell disease, OR
  - Neurodevelopmental disorders, for example, cerebral palsy, OR
  - A medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
  - Asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

The monoclonal antibodies are not authorized for use in patients

- Who are hospitalized due to COVID-19, OR
- Who require oxygen therapy due to COVID-19, OR
- Who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.

Treatment of monoclonal antibodies for COVID-19 should be given as soon as possible after a positive COVID-19 test and **within 10 days of symptom onset.** Patients should continue to self-isolate and use infection control measures according to CDC guidelines. Treatment regimen is one dose.

Patients should be clinically monitored during and after infusion or injections for at least one hour.

Providers of these monoclonal antibodies must agree to report usage, provide certain information to patients, and submit required documentation. A complete list of requirements can be found on the Healthcare Fact Sheets

CMS reimbursement rates for monoclonal antibody administration can be found at: https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies

More information about COVID-19 treatment options, including EUA Fact Sheets, can be found at: https://combatcovid.hhs.gov/i-have-covid-19-now/available-covid-19-treatment-options

Providers of monoclonal antibodies for COVID-19 treatment can be found at: https://covid.infusioncenter.org/

CASIRIVIMAB/IMDEVIMAB (REGEN-COV)
Dose: 600 mg of casirivimab and 600 mg of imdevimab as a one-time dose.

Approved for intravenous infusion and subcutaneous injection when intravenous administration is not feasible and would lead to delay in treatment.

Minimum infusion times for intravenous administration are 20 to 50 minutes, depending on the size of Sodium Chloride bag used.

When giving by subcutaneous injection, four syringes containing 2.5 ml each should be given at four different injections sites into the thigh, back of upper arm, or abdomen, except for 2 inches around the navel, using different quadrants. The waistline should be avoided.

New and existing providers can order REGEN-COV via the AmerisourceBergen C19 Therapies Direct Order Request at no charge: https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8

SOTROVIMAB
Dose: 500 mg by intravenous infusion over 30 minutes

Sotrovimab is available **for purchase** directly with AmerisourceBergen using existing AmerisourceBergen accounts or by calling Customer Service (1-800-746-6273) or emailing c19therapies@amerisourcebergen.com. More information can be found on the sotrovimab website: https://www.sotrovimab.com

BAMLANIVIMAB/ETESEVIMAB
Distribution of bamlanivimab/etesevimab (Lilly product) has been paused due to its lack of activity against the Beta and Gamma variants of the COVID-19 virus.